

### REMARKS

This document is filed in reply to the Office Action dated July 13, 2004 ("Office Action"). Applicants have amended claim 24 to promote clarity. Support for the amendment can be found at, e.g., page 10, lines 12-21 of the specification.<sup>1</sup> No new matter has been introduced.

**The amendments should be entered as they raise no new issues that will require further consideration or search and also do not touch the merits of the application within the meaning of 37 C.F.R. § 1.116(b).**

Claims 24-27 are pending. Reconsideration of this application is requested in view of the following remarks:

The Examiner rejected claim 24 for being anticipated by Lukac et al., *Infect. Immun.* 56: 3095-3098, 1988 ("Lukac"). See the Office Action, page 3, lines 23-25. Applicants respectfully traverse.

Claim 24 covers an isolated nucleic acid encoding a non-toxic polypeptide that contains (i) a *Pseudomonas* exotoxin A receptor binding domain and (ii) a fragment **heterologous to *Pseudomonas* exotoxin A** having at least two copies of an antigenic peptide sequence.

Lukac teaches a nucleic acid encoding a full-length *Pseudomonas aeruginosa* exotoxoid A (ETA) mutant polypeptide that lacks glutamic acid-553. See Lukac, the paragraph bridging pages 3095 and 3096. According to the Examiner, this polypeptide contains (i) the receptor binding domain recited in claim 24, and (ii) an ETA fragment having two antigenic ala-ala-gly-glu repeats (at position 375-378 and 523-526 of the ETA). As such, she concluded that Lukac teaches the claimed nucleic acid.

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<sup>1</sup> According to this passage of the specification, "[A] DNA fragment encoding 12 repeats of [antigenic] GnRH was subcloned into plasmid pPEDI, which was produced by subcloning the sequence encoding domain Ia of PE in pJH4," to generate plasmid pPEDIG12 for expressing a fusion protein (PE Ia-GnRH12). This fusion protein thus includes (i) the receptor binding domain (i.e., domain Ia) of *Pseudomonas* exotoxin A and (ii) a fragment having 12 copies of GnRH repeats, which are antigenic. As GnRH is not derived from *Pseudomonas* exotoxin A, a GnRH repeat-containing fragment is heterologous to *Pseudomonas* exotoxin A. Note that the phrase "heterologous to *Pseudomonas* exotoxin A." does not have to be set forth verbatim in the specification. In *In re Wright*, 9 USPQ2d 1649 (Fed. Cir. 1989), the Federal Circuit, in reversing a Board's 35 U.S.C. § 112, first paragraph rejection, held that there was adequate written description support for applicant's claim limitation, despite the fact that it was not set forth "*in haec verba*" (i.e., "in these words" or "verbatim") in the specification.

Applicants disagree. As correctly acknowledged by Examiner, the ala-ala-gly-glu repeat-containing fragment taught in Lukac is a part of the ETA polypeptide. See, the Office Action, page 4, lines 10-21. In other words, this fragment is **not heterologous to *Pseudomonas* exotoxin A**. In contrast, the fragment recited in claim 24 is **heterologous to *Pseudomonas* exotoxin A**. Thus, the nucleic acid of claim 24, which encodes the polypeptide, is novel over Lukac.

#### CONCLUSION

Applicants submit that grounds for the rejections asserted by the Examiner have been overcome, and that claims, as pending, define statutory subject matter that is novel. On this basis, it is submitted that allowance of this application is proper, and early favorable action is solicited.

Please apply any other charges to deposit account 06-1050, referencing the attorney docket 08919-022001.

Respectfully submitted,

Date: \_\_\_\_\_

8-25-04



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